

Notice of Allowability

Application No.

09/486,613

Examiner

Abigail M. Cotton

Applicant(s)

MASH, DEBORAH C.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/2/2006.
2. ☒ The allowed claim(s) is/are 6-9, 25 and 27-30.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

REASONS FOR ALLOWANCE

This action is in response to the after final amendment submitted on November 2, 2006.

The Examiner notes that Applicant has adopted the Examiner's proposed amendments to the claims as set forth in the Final Rejection mailed on June 27, 2006, which amendments are considered sufficient to overcome the rejection of the claims under 35 U.S.C. 112, first paragraph, and the rejections of the claims under 35 U.S.C. 103(a) over the reference to Bagal et al. Applicant has also provided a declaration under 37 C.F.R. 1.132 that is sufficient to overcome the rejections made under 35 U.S.C. 103(a) over the reference to Pablo et al. Applicants have also amended claims 27 and 28, thereby obviating the objection to the typo-type errors in these claims. Accordingly, claims 6-9, 25 and 27-30 are considered to be in condition for allowance.

The following is an examiner's statement of reasons for allowance:

Applicants have amended the preamble of the claims in accordance with the Examiner's proposal to recite a method of treating a patient to alleviate "nociceptive pain in the absence of the treatment of drug dependency or drug abuse", which amendments are supported in the instant specification on page 8, lines 5-20, where it is disclosed that the noribogaine can be administered "either for the treatment of pain or

Art Unit: 1617

for the treatment of drug dependency or abuse,” and thus positively recites the treatment of either pain, as in the proposed claim, or drug dependency or abuse, as is excluded from the proposed claim. According to MPEP 2173.05 “any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recite in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977.)” The Examiner furthermore notes that the originally-filed abstract discloses that the invention is directed to “methods of treating patients for pain.” Thus, the amendment is considered to be sufficient to overcome the rejection under 35 U.S.C. 112, first paragraph, for new matter.

Applicant’s amendment is also sufficient to overcome the rejections over Bagal et al. because Bagal only teaches that the noribogaine is provided in combination with morphine, an analgesic, to improve the antinociceptive activity of the morphine. Bagal et al. does not teach or suggest that noribogaine has analgesic properties itself or would be otherwise capable of providing pain relief in the absence of any other analgesic such as morphine. Thus, one of ordinary skill in the art at the time the invention was made would not have had any motivation, based on the teachings of Bagal et al or other similar references, to provide the noribogaine as the sole analgesic agent for the treatment of nociceptive pain, and in the absence of the treatment of drug dependency or drug abuse. Accordingly, the claimed methods are considered to be allowable over

Art Unit: 1617

prior art teachings that merely teach enhanced antinociceptive activity of morphine with co-administration of noribogaine.

The Examiner furthermore notes that, as discussed in the Final Rejection mailed on June 27, 2006, Applicant claims a method that is for treating a patient to alleviate nociceptive pain, and thus distinguishes over previously cited references such as that to Olney (of record) that are directed to the treatment of neuropathic pain using NMDA receptor agonists. Applicant has presented evidence in the declaration filed December 22, 2005, showing that neuropathic pain is recognized as a class of pain that is distinct from nociceptive pain. For example, while opioid agonists are known to be useful in the treatment of nociceptive pain, neuropathic pain is mediated through NMDA receptors and does not conventionally respond to opiates (see paragraph 28 of Declaration filed December 22, 2005, in particular.) Applicant has also cited art that distinguishes between neuropathic and nociceptive pain and conventional treatments therefore (see, e.g., the article entitled "Neuropathic Pain in Cancer Patients: Mechanisms, Syndromes and Clinical Controversies," by Martin et al, 1997, the Journal of Pain and Symptom Management, of record, et al.) Support for the alleviation of "nociceptive pain" is found on page 9, final full paragraph of the instant specification, which discloses that noribogaine is an "antinociceptive agent." Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would not have found it obvious to treat of nociceptive pain with noribogaine in view of prior teachings of

Art Unit: 1617

neuropathic pain treatment, and thus the claimed methods are considered to be allowable over such teachings.

The Examiner furthermore notes that Applicant has filed a declaration under 37 C.F.R. 1.132 and signed by the inventor of the instant application, Deborah C. Mash, on October 31, 2006, stating that Dr. Mash originated the hypothesis and experimental design of the experiments that gave rise to the Pablo et al. paper (of record) that was cited as prior art against the instant claims. The declaration states that Dr. Mash also directed and supervised Mr. Pablo, who was a graduate student in Dr. Mash's laboratory, while the experiments were being conducted, and Dr. Mash was responsible for drawing the conclusions from the data obtained by the experiments. The Examiner notes that a declaration under 37 CFR 1.132 establishing that applicant is the sole inventor and that others were merely working under his or her direction is sufficient to remove a publication as a reference under 35 U.S.S. 102(a). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (see also MPEP 715.01(c)(I).) Accordingly, as the Pablo et al. article was co-authored by Dr. Mash and Mr. Pablo, and was cited as prior art only under the qualifying provisions of 35 U.S.C. 102(a), the article is being withdrawn as a prior art in view of Applicant's declaration.

Accordingly, the instant claims are considered to be allowable because the prior art does not teach or suggest a method of treating a patient to alleviate nociceptive

Art Unit: 1617

pain, where the treatment is in the absence of the treatment of drug dependency or drug abuse, and wherein the noribogaine or its salt is the sole analgesic administered.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

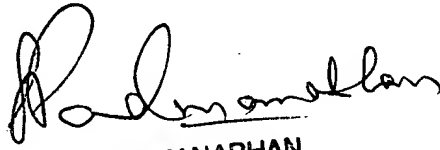
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER